March 30, 2020

Jerry Medical Instrument (Shanghai) Co., Ltd.
% Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.608, No.738, Shangcheng Rd., Pudong
Shanghai, China 200120

Re: K192658
Trade/Device Name: Manual Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR
Dated: January 5, 2020
Received: February 20, 2020

Dear Boyle Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Heather Dean, Ph.D.
Acting Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192658

Device Name
Manual Wheelchair

Indications for Use *(Describe)*
The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

1.0 Submitter's information

Name: JERRY MEDICAL INSTRUMENT (SHANGHAI) CO., LTD.
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Contact: Jianguo Chen
Date of Preparation: Sep.20, 2019

Designated Submission Correspondent

Mr. Boyle Wang
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Tel: +86-21-50313932
Email: Info@truthful.com.cn

2.0 Device information

Trade name: Manual Wheelchair
Common name: Mechanical Wheelchair
Classification name: Wheelchair, Mechanical
Model(s): JR201, JR202, JR203, JR204

3.0 Classification

Production code: IOR
Regulation number: 21 CFR 890.3850
Classification: Class I
Panel: Physical Medicine

4.0 Predicate device information

Manufacturer: JIANGYIN NEWRISE MEDICAL EQUIPMENT CO., LTD.
Device: Manual Wheelchair
510(k) number: K180852

5.0 Indication for Use Statement

The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

6.0 Device description

The proposed device, Manual Wheelchair, driven by manual operation of rear tire, or pushed by caretaker.

This product is mainly designed to be used to take care of the disabled or elderly, it is driven by manual operation of rear tire, or pushed by caretaker.

The Manual Wheelchair consists of Frame, Footplate, Front castor, Rear wheel, Anti-tipper, Armrest, Brake, Central fork.

The Manual Wheelchair has four models: JR201, JR202, JR203, JR204.

- JR201: 6 inch front wheel and 22 inch rear tire, without height adjustable armrest, flip-up armrest, detachable footrest, connecting brake
- JR202: 6 inch front wheel and 22 inch rear tire, with height adjustable armrest, flip-up armrest, detachable footrest, connecting brake
- JR203: 8 inch front wheel and 24 inch rear tire,, without height adjustable armrest, flip-up armrest, detachable footrest, connecting brake
- JR204: 8 inch front wheel and 24 inch rear tire, with height adjustable armrest, flip-up armrest, detachable footrest, connecting brake

Max. loading can not be over than 100Kgs.

7.0 Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

16-195 ISO 7176-1 Third edition 2014-10-01
Wheelchairs - Part 1: Determination of static stability
16-192 ISO 7176-3 Third edition 2012-12-15
Wheelchairs - Part 3: Determination of effectiveness of brakes
16-163 ISO 7176-5 Second edition 2008-06-01
Wheelchairs - Part 5: Determination of overall dimensions, mass and manoeuvring space
16-196 ISO 7176-7 First Edition 1998-05-15
Wheelchairs - Part 7: Measurement of seating and wheel dimensions
16-197 ISO 7176-8 Second editon 2014-12-15
Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue

strengths
16-190 ISO 7176-11 Second edition 2012-12-01
Wheelchairs - Part 11: Test dummies
16-25 ISO 7176-13 First edition 1989-08-01
Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces
16-27 ISO 7176-15 First edition 1996-11-15
Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling
16-191 ISO 7176-16 Second edition 2012-12-01
Wheelchairs - Part 16: Resistance to ignition of postural support devices
16-198 ISO 7176-22 Second edition 2014-09-01
Wheelchairs - Part 22: Set-up procedures
ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

8.0 Clinical Test Conclusion

No clinical study implemented for the mechanical wheelchair.

9.0 Technological Characteristic Comparison Table

Table1-General Comparison

Item	Proposed device	Predicated device	Remark
Product Code	IOR	IOR	SE
Regulation No.	21 CFR 890.3850	21 CFR 890.3850	SE
Class	I	I	SE
Product name	Manual Wheelchair	Manual Wheelchair	-
510(k) No.		K180852	-
Models	JR201, JR202, JR203, JR204	XSG106A	-
Intended Use	The device is intended for medical purposes to provide mobility to persons restricted to a sitting position	The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.	SE
Use environment	Indoor, outdoor	Indoor, outdoor	SE
Patient Population	Disabled and elderly people (less than 100kg)	Disabled or an elderly person	* Gap 1
Product structure	Frame, Footplate, Front castor, Rear wheel, Anti-tipper, Armrest, Brake,	Frame, Footplate, Front castor, Rear wheel, Anti-tipper, Armrest, Brake,	SE

	Central fork	Central fork	
Height adjustable	With height adjustable, or, without height adjustable	No height adjustable	*Gap 2
Driving system	Driven by manual operation of rear tire, or pushed by caretaker.	Driven by manual operation of rear tire, or pushed by caretaker.	SE
Footplate	Yes	Yes	SE
Number of wheels	4	4	SE
Main frame material	Aluminium alloy	Aluminium alloy	SE

* Gap analysis:

Gap 1: the two device share same target population, but the proposed device has stricter scope, only for whose weight is less than 100kg, which is defined in the product intended use, and the predicate device does not demonstrate this limit. After clarification in the product intended use, the difference can not raise additional safety concerns.

Gap 2: the models of JR201, JR202, JR203, R204 have difference in armrest type (with height adjustable, or, without height adjustable), the predicate device’s armrest is without height adjustable. The difference in height adjustable does not bring additional safety and effectiveness concerns;

Table2 Performance Comparison

Item	Proposed Device				Predicate Device	Remark
	JR201	JR202	JR203	JR204		
Braking system	Connecting brake				Connecting brake	SE
Max. loading (kg)	100				100	SE
Overall dimensions	1000*530*970 mm	1000*530*970 mm	1015*655*955 mm	1015*655*955 mm	1030*640*930 mm	* Gap 3
Seat dimension	Depth:435 mm Height:445 mm Width: 410/450/510 mm	Depth:435 mm Height:445 mm Width: 410/450/510 mm	Depth:435 mm Height:500 mm Width: 410/450/510 mm	Depth:435 mm Height:500 mm Width: 410/450/510 mm	Depth: 460 mm Height: 420 mm Width: 410 mm	* Gap 4
Rear wheel	Size: 22 inch Tire: no pneumatic	Size: 22 inch Tire: no pneumatic	Size: 24 inch Tire: no pneumatic	Size: 24 inch Tire: no pneumatic	Size: 610 mm Tire: no pneumatic	* Gap 5
Wheel lock	Push-to-Lock	Push-to-Lock	Push-to-Lock	Push-to-Lock	Pull-to-Lock	* Gap 6
Ground clearance	70mm	70mm	70mm	70mm	150mm	* Gap 7
Armrest	Without height adjustable	Height adjustable	Without height adjustable	Height adjustable	Without height adjustable	* Gap 8
Casters (front wheel)	Size: 6 inch	Size: 6 inch	Size: 8 inch	Size: 8 inch	Size: 200mm	* Gap 9
Static stability (forward, with non-lockable front wheels)	15°	15°	15°	15°	17°	* Gap 10

Static stability (rearward, with non-lockable rear wheels)	15°	15°	15°	15°	17°	* Gap 11
Static stability (rearward, with lockable rear wheels)	13.1°	13.1°	13.1°	13.1°	16°	* Gap 12
Static stability (lateral forward, Left/Right)	15°	15°	15°	15°	16°	* Gap 13
Parking brakes (Facing downhill, Facing uphill)	15°	15°	15°	15°	16°	* Gap 14
Min. Turning back diameter	1700mm	1700mm	1700mm	1700mm	1700mm	SE
Net Weight	14.8 kgs	15 kgs	16.3 kgs	16.5 kgs	18kg	* Gap 15
Anti-tip wheels	Removable	Removable	Removable	Removable	Removable	SE
Suspension	No	No	No	No	No	SE

* Gap analysis:

Gap 3-5, the two devices have different dimensions, rear wheel size, this specification is only affects the appearance of the device, it could not affects the safety and effectiveness of proposed device. All performances of proposed device are meet the design specification and been conducted into performance test, so the subject device is as safe, as effective, and performs as well as the legally marketed predicate device;

Gap 6, the two devices have different wheel lock, which only influence the operation method: pull or push, it does not create additional safety and effectiveness concerns;

Gap 7, the two devices have different ground clearance, which impact the trafficability characteristic, but not affects the safety and effectiveness of proposed device, the ground clearance of proposed device is approved by its test report;
Gap 8, the models of JR201, JR202, JR203, R204 have difference in armrest adjusting (with height adjustable, or, without height adjustable), the predicate device's armrest is without height adjustable. The difference in height adjustable, only lie one more function, does not bring additional safety and effectiveness concerns;
Gap 9, the different specification in caster size is only affects the appearance of the device, it could not affects the safety and effectiveness of proposed device;
Gap 10-14, the static stability of the proposed device is little lower than the predicate device, both of them is enough for usual using condition, the difference does not raise additional safety and effectiveness concerns;
Gap 15, the net weight of proposed device is lower than the predicate device, but is close, the difference does not raise additional safety and effectiveness concerns.

Table3 Safety Comparison

Item	Proposed Device	Predicate Device	Remark
Performance test	ISO 7176-1:2014, ISO 7176-3:2012, ISO 7176-5 :2008, ISO 7176-7:1998, ISO 7176-8:2014, ISO 7176-11:2012, ISO 7176-13:1989, ISO 7176-15:1996, ISO 7176-16:2012, ISO 7176-22:2014.	ISO 7176-1:2014, ISO 7176-3:2012, ISO 7176-5 :2008, ISO 7176-7:1998, ISO 7176-8:2014, ISO 7176-11:2012, ISO 7176-13:1989, ISO 7176-15:1996, ISO 7176-16:2012, ISO 7176-22:2014.	SE
Main materials	Frame, Anti-tip, Central fork: Aluminium alloy; Armrest: PU; Casters: PP+30%GF+PU; Rear wheel: hub+spoke(36 pcs) +aluminium alloy hand rim; Backrest: oxford cloth; Brake: Steel	Frame: Aluminium alloy; Wheel, Armrest: PU; Rear Wheel: PU Solid Material Casters: PVC Solid Material	* Gap 16
Materials contacting user	Armrest: PU; Inner cushion: oxford cloth	Armrests, Seat Base, Back Cover: Artificial leather	* Gap 16
Biocompatibility of materials contacting user	Comply with ISO 10993-1, FDA Guidance, Tests included Cytotoxicity (ISO 10993-5:2009), Sensitization and Intracutaneous Reactivity (ISO 10993-10:2010)	Comply with ISO 10993-1, FDA Guidance, Tests included Cytotoxicity (ISO 10993-5:2009), Sensitization and Intracutaneous Reactivity (ISO 10993-10:2010)	SE
Label and Labeling	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	SE

* Gap analysis:

Gap 16, the two devices have different materiasl on the Armrests, Seat Base, Back Cover, the two materials has passed the bio-compatibility tested on Cytotoxicity, Sensitization and Intracutaneous Reactivity based on the same test standards: ISO 10993-5:2009, and ISO 10993-10:2010; therefore, no safety and effectiveness concerns raised.

10.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the proposed device is as safe, as effective, and performs as well as the legally marketed predicated device and raises no new questions of safety or effectiveness.The differences between both devices are insignificant in terms of safety and effectiveness.